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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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JORGE CASANOVA,

Plaintiff,

-against-

MERCK & CO., INC.,

Defendant.
----- x

No.: 07 Civ 7415

**ANSWER AND JURY DEMAND
OF DEFENDANT MERCK &
CO., INC.**

Defendant Merck & Co., Inc. ("Merck") by its undersigned attorneys, answers the Verified Complaint ("Complaint") herein as follows:

1. Denies each and every allegation contained in paragraph 1 of the Complaint except admits that Merck manufactured the prescription medicine Vioxx and that Plaintiff purports to bring an action for certain damages but denies that there is any legal or factual basis for relief.

2. Denies each and every allegation contained in paragraph 2 of the Complaint.

3. Denies each and every allegation contained in paragraph 3 of the Complaint except admits that on September 27, 2004 Merck contacted the FDA and advised the

FDA that the APPROVe clinical trial had been halted and respectfully refers the Court to the referenced study for its actual language and full text.

4. Denies each and every allegation contained in paragraph 4 of the Complaint except admits that Merck sought and received FDA approval to manufacture and market the prescription medicine Vioxx.

5. Denies each and every allegation contained in paragraph 5 of the Complaint except admits that the studies referenced in the first sentence of paragraph 5 and the article referenced in the second sentence of paragraph 5 exist, and respectfully refers the Court to said publications for their actual language and full text.

6. Denies each and every allegation contained in paragraph 6 of the Complaint except admits that Plaintiff purports to quote portions of certain of Merck's Annual Reports and respectfully refers the Court to the referenced Annual Reports for their actual language and full text.

7. Denies each and every allegation contained in paragraph 7 of the Complaint except admits that the referenced study exists and respectfully refers the Court to said study for its actual language and full text.

8. Denies each and every allegation contained in paragraph 8 of the Complaint except admits that the referenced study and press release exist and respectfully refers the Court to the referenced study and press release for their actual language and full text.

9. Denies each and every allegation contained in paragraph 9 of the Complaint, except admits that on September 30, 2004 Merck announced the voluntary worldwide withdrawal of Vioxx. Merck further avers that in a prospective, randomized, placebo controlled clinical trial there was an increased relative risk for confirmed cardiovascular

events beginning after eighteen months of treatment in the patients taking Vioxx compared with those taking placebo and given the availability of alternative therapies and questions raised by the data from that trial, Merck concluded that the voluntary withdrawal of Vioxx best served the interests of patients.

10. The allegations contained in paragraph 10 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.

11. Upon information and belief, admits the allegations contained in paragraph 11 of the Complaint.

12. Denies each and every allegation contained in paragraph 12 of the Complaint except admits that Merck is a New Jersey Corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey and is authorized to do business in the State of New York.

13. Admits that Vioxx is Merck's trade name for rofecoxib.

14. Admits the allegation contained in paragraph 14 of the Complaint that Merck is the owner of the registered trademark Vioxx.

15. Denies each and every allegation contained in paragraph 15 of the Complaint except admits that Merck manufactured, marketed, and distributed the prescription medicine Vioxx and that Merck is authorized to do business in the State of New York.

16. Denies each and every allegation contained in paragraph 16 of the Complaint except admits that Merck distributed the prescription medicine Vioxx.

17. Denies each and every allegation contained in paragraph 17 of the Complaint.

18. Denies each and every allegation contained in paragraph 18 of the Complaint.

19. Denies each and every allegation contained in paragraph 19 of the Complaint.

20. Denies each and every allegation contained in paragraph 20 of the Complaint.

21. Denies each and every allegation contained in paragraph 21 of the Complaint.

**RESPONSE TO "COUNT ONE
FALSE & DECEPTIVE TRADE PRACTICES"**

22. With respect to the allegations contained in paragraph 22 of the Complaint, Merck repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 21 of this Answer with the same force and effect as though set forth here in full.

23. The allegations contained in paragraph 23 of the Complaint are legal conclusions and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph and respectfully refers the Court to the referenced statute for its actual language and full text.

24. Denies each and every allegation contained in paragraph 24 of the Complaint.

25. The allegations contained in paragraph 25 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.

26. Denies each and every allegation contained in paragraph 26 of the Complaint.

27. Denies each and every allegation contained in paragraph 27 of the Complaint.

28. The allegations contained in paragraph 28 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.

29. Denies each and every allegation contained in paragraph 29 of the Complaint.

**RESPONSE TO “COUNT TWO
NEGLIGENCE”**

30. With respect to the allegations contained in paragraph 30 of the Complaint, Merck repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 29 of this Answer with the same force and effect as though set forth here in full.

31. Denies each and every allegation contained in paragraph 31 of the Complaint.

32. Denies each and every allegation contained in paragraph 32 of the Complaint.

33. Denies each and every allegation contained in paragraph 33 of the Complaint.

34. Denies each and every allegation contained in paragraph 34 of the Complaint.

**RESPONSE TO “COUNT THREE
STRICT LIABILITY”**

35. With respect to the allegations contained in paragraph 35 of the Complaint, Merck repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 34 of this Answer with the same force and effect as though set forth here in full.

36. Denies each and every allegation contained in paragraph 36 of the Complaint except admits that Merck manufactured, marketed, and distributed the prescription medicine Vioxx.

37. Denies each and every allegation contained in paragraph 37 of the Complaint.

38. Denies each and every allegation contained in paragraph 38 of the Complaint.

39. Denies each and every allegation contained in paragraph 39 of the Complaint.

**RESPONSE TO “COUNT FOUR
BREACH OF IMPLIED WARRANTY”**

40. With respect to the allegations contained in paragraph 40 of the Complaint, Merck repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 39 of this Answer with the same force and effect as though set forth here in full.

41. The allegations contained in paragraph 41 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph except admits that Merck manufactured, marketed, and distributed the prescription medicine Vioxx.

42. Denies each and every allegation contained in paragraph 42 of the Complaint.

43. Denies each and every allegation contained in paragraph 43 of the Complaint.

44. Denies each and every allegation contained in paragraph 44 of the Complaint.

**RESPONSE TO “COUNT FIVE
BREACH OF EXPRESS WARRANTY”**

45. With respect to the allegations contained in paragraph 45 of the Complaint, Merck repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 44 of this Answer with the same force and effect as though set forth here in full.

46. Denies each and every allegation contained in paragraph 46 of the Complaint.

47. Denies each and every allegation contained in paragraph 47 of the Complaint.

**RESPONSE TO "COUNT SIX
FALSE ADVERTISING"**

48. With respect to the allegations contained in paragraph 48 of the Complaint, Merck repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 47 of this Answer with the same force and effect as though set forth here in full.

49. The allegations contained in paragraph 49 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph and respectfully refers the Court to the referenced statute for its actual language and full text.

50. Denies each and every allegation contained in paragraph 50 of the Complaint.

51. Denies each and every allegation contained in paragraph 51 of the Complaint.

**RESPONSE TO "COUNT SEVEN
FRAUD"**

52. With respect to the allegations contained in paragraph 52 of the Complaint, Merck repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 51 of this Answer with the same force and effect as though set forth here in full.

53. Denies each and every allegation contained in paragraph 53 of the Complaint.

54. Denies each and every allegation contained in paragraph 54 of the Complaint.

55. Denies each and every allegation contained in paragraph 55 of the Complaint.

56. Denies each and every allegation contained in paragraph 56 of the Complaint.

57. Denies each and every allegation contained in paragraph 57 of the Complaint.

58. Denies each and every allegation contained in paragraph 58 of the Complaint.

59. Paragraph 59 of the Complaint is not an allegation of fact and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation in paragraph 59 of Plaintiff's Complaint and denies that Plaintiff is entitled to the relief requested.

60. Paragraph 60 of the Complaint is not an allegation of fact and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation in paragraph 60 of Plaintiff's Complaint and denies that Plaintiff is entitled to the relief requested.

61. Paragraph 61 of the Complaint is not an allegation of fact and therefore no responsive pleading is required.

**AS FOR A FIRST
DEFENSE, MERCK ALLEGES:**

62. The claims of Plaintiff may be time-barred, in whole or in part, under applicable statutes of limitations or statutes of repose, or are otherwise untimely.

**AS FOR A SECOND
DEFENSE, MERCK ALLEGES:**

63. The Complaint fails to state a claim upon which relief can be granted.

**AS FOR A THIRD
DEFENSE, MERCK ALLEGES:**

64. The claims of Plaintiff may be barred, in whole or in part, from recovery because he has made statements or taken actions that preclude him from asserting claims or constitute a waiver of his claims.

**AS FOR A FOURTH
DEFENSE, MERCK ALLEGES:**

65. The claims of Plaintiff may be barred, in whole or in part, from recovery because of the res judicata effect of prior judgments.

**AS FOR A FIFTH
DEFENSE, MERCK ALLEGES:**

66. Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

**AS FOR A SIXTH
DEFENSE, MERCK ALLEGES:**

67. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

**AS FOR A SEVENTH
DEFENSE, MERCK ALLEGES:**

68. To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable federal laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

**AS FOR AN EIGHTH
DEFENSE, MERCK ALLEGES:**

69. To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of Vioxx, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warning to the prescribing physician.

**AS FOR A NINTH
DEFENSE, MERCK ALLEGES:**

70. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only so sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

**AS FOR A TENTH
DEFENSE, MERCK ALLEGES:**

71. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

**AS FOR AN ELEVENTH
DEFENSE, MERCK ALLEGES:**

72. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of Vioxx.

**AS FOR A TWELFTH
DEFENSE, MERCK ALLEGES:**

73. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and unrelated medical, genetic and environmental conditions, diseases, or illnesses, subsequent medical conditions or natural courses of conditions for which this defendant is not responsible.

**AS FOR A THIRTEENTH
DEFENSE, MERCK ALLEGES:**

74. To the extent Plaintiff has settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

**AS FOR A FOURTEENTH
DEFENSE, MERCK ALLEGES:**

75. To the extent Plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

**AS FOR A FIFTEENTH
DEFENSE, MERCK ALLEGES:**

76. Plaintiff's claims of fraud and misrepresentation are barred by reason of Plaintiff's failure to allege the circumstances constituting fraud with particularity, as required by Sections 3013 and 3016(b) of the New York Civil Practice Law and Rules and Rule 9(b) of the Federal Rules of Civil Procedure.

**AS FOR A SIXTEENTH
DEFENSE, MERCK ALLEGES:**

77. Plaintiff's claims are barred, in whole or in part, under the applicable state law because Vioxx was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

**AS FOR A SEVENTEENTH
DEFENSE, MERCK ALLEGES:**

78. Plaintiff's claims are barred in whole or in part by the First Amendment.

**AS FOR AN EIGHTEENTH
DEFENSE, MERCK ALLEGES:**

79. Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

**AS FOR A NINETEENTH
DEFENSE, MERCK ALLEGES:**

80. There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of Vioxx.

**AS FOR A TWENTIETH
DEFENSE, MERCK ALLEGES:**

81. The claims of Plaintiff may be barred, in whole or in part, from recovery because, in this or other courts, he has brought actions and has received judgments on parts of some or all claims asserted herein.

**AS FOR A TWENTY-FIRST
DEFENSE, MERCK ALLEGES:**

82. The claims of Plaintiff may be barred, in whole or in part, from recovery, on the ground that the claims asserted herein have been submitted to arbitration, and a binding decision has been rendered.

**AS FOR A TWENTY-SECOND
DEFENSE, MERCK ALLEGES:**

83. The claims of Plaintiff may be barred, in whole or in part, from recovery by release as to his claims.

**AS FOR A TWENTY-THIRD
DEFENSE, MERCK ALLEGES:**

84. The claims of Plaintiff may be barred, in whole and in part, by the doctrine of laches.

**AS FOR A TWENTY-FOURTH
DEFENSE, MERCK ALLEGES:**

85. The claims of Plaintiff are barred, in whole or in part, by his failure to mitigate damages.

**AS FOR A TWENTY-FIFTH
DEFENSE, MERCK ALLEGES:**

86. To the extent there were any risks associated with the use of the product which is the subject matter of this action that Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and governing state laws.

**AS FOR A TWENTY-SIXTH
DEFENSE, MERCK ALLEGES:**

87. The claims of Plaintiff may be barred, in whole or in part, from recovery, due to spoliation of evidence.

**AS FOR A TWENTY-SEVENTH
DEFENSE, MERCK ALLEGES:**

88. The claims of Plaintiff may be barred, in whole or in part, by the governing state laws.

**AS FOR A TWENTY-EIGHTH
DEFENSE, MERCK ALLEGES:**

89. Any conduct allegedly causing liability on the part of Merck is not a substantial cause or factor of any potential or actual injury or damage, if any.

**AS FOR A TWENTY-NINTH
DEFENSE, MERCK ALLEGES:**

90. Plaintiff has not sustained any injury or damages compensable at law.

**AS FOR A THIRTIETH
DEFENSE, MERCK ALLEGES:**

91. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, such an award would also, if granted, violate Merck's state and federal constitutional rights.

**AS FOR A THIRTY-FIRST
DEFENSE, MERCK ALLEGES:**

92. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless, or grossly negligent and, therefore, any award of punitive damages is barred.

**AS FOR A THIRTY-SECOND
DEFENSE, MERCK ALLEGES:**

93. Plaintiff's demand for punitive damages is barred because Vioxx and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**AS FOR A THIRTY-THIRD
DEFENSE, MERCK ALLEGES:**

94. Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

**AS FOR A THIRTY-FOURTH
DEFENSE, MERCK ALLEGES:**

95. Plaintiff's claims are barred in whole or in part because Merck provided adequate "directions or warnings" as to the use of Vioxx and any other drug or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

**AS FOR A THIRTY-FIFTH
DEFENSE, MERCK ALLEGES:**

96. Plaintiff's claims are barred under Section 4, et. seq., of the Restatement (Third) of Torts: Products Liability.

**AS FOR A THIRTY-SIXTH
DEFENSE, MERCK ALLEGES:**

97. Plaintiff's claims are barred in whole or in part because Vioxx "provides net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

**AS FOR A THIRTY-SEVENTH
DEFENSE, MERCK ALLEGES:**

98. Plaintiff's claims are barred by the doctrine of contributory negligence.

**AS FOR A THIRTY-EIGHTH
DEFENSE, MERCK ALLEGES:**

99. Plaintiff's claims under New York General Business Law Section 349 are barred by reason of Plaintiff's failure to allege sufficient facts identifying any statement or misrepresentation alleged to constitute a deceptive act or practice and his failure to plead causation with sufficient specificity.

**AS FOR A THIRTY-NINTH
DEFENSE, MERCK ALLEGES:**

100. Merck's conduct and all activities with respect to the subject product were fair and truthful based upon the knowledge existing at the relevant time alleged in the Complaint. Therefore, Plaintiff's claims under New York Business Corporation Law § 349 are barred.

**AS FOR A FORTIETH
DEFENSE, MERCK ALLEGES:**

101. Plaintiff's claims under New York General Business Law Section 350 are barred by reason of Plaintiff's failure to allege sufficient facts identifying any statement or misrepresentation alleged to constitute false advertising and his failure to plead causation or reliance with sufficient specificity.

**AS FOR A FORTY-FIRST
DEFENSE, MERCK ALLEGES:**

102. Any injuries, losses or damages suffered by Plaintiff were proximately caused, in whole or in part, by the failure of Plaintiff to exercise ordinary care and to follow the advice, information, warnings and/or instructions provided with the subject pharmaceutical product and therefore Plaintiff's recovery, if any, must be diminished by the proportion of the negligence of Plaintiff which proximately caused or contributed to the alleged injuries, losses or damages.

**AS FOR A FORTY-SECOND
DEFENSE, MERCK ALLEGES:**

103. Plaintiff's claims are barred in whole or in part because the product at issue was not defective at the time that it left Merck's control.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and supplement the averments of its answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery of this action.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck its reasonable costs and disbursements, together with such and other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York
August 20, 2007

Respectfully submitted,

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